

EU DECLARATION OF CONFORMITY – CELLEDGE TRIMMING BLADES

Date: 27/07/2021

This Declaration of Conformity has been issued solely by CellPath Limited (Company Number 01831261) in accordance with the definitions and regulations as described in the **EU Regulation 2017/746 of The European Parliament and of the Council on In-Vitro Diagnostic Medical Devices**.

General Information

Manufacturer	CellPath Limited
Address of Production Facility	CellPath Ltd Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Histology/pathology tissue knife blade IVD
Product Description	A flat instrument with a sharp edge intended to be fixed onto a handle (not included) to create a knife for cutting and/or slicing human tissues in a histopathology laboratory for subsequent in vitro diagnostic investigation. It is typically made of stainless steel. This is a reusable device.
Product Classification <i>(Classified in accordance with EU Regulation 2017/746)</i>	CLASS A

Registered Office:

CellPath Ltd, 80 Mochdre Enterprise Park,
Newtown, Powys, SY16 4LE Mid Wales, UK
Registration Number: 01831261

DEVICE(S) INFORMATION

PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
CAH-0100-00A	05056256106282	05056256CAH001WR	CELLEDGE T130 TRIMMING BLADES - 50 BLADES	2019
CAH-0100-00S	05056256107739	05056256CAH001WR	CELLEDGE T130 TRIMMING BLADES - 5 BLADES	2019
CAH-0200-00A	05056256106374	05056256CAH001WR	CELLEDGE T260 TRIMMING BLADES - 50 BLADES	2019
CAH-0200-00S	05056256107722	05056256CAH001WR	CELLEDGE T260 TRIMMING BLADES - 5 BLADES	2019

Conformity to the aforementioned regulation is demonstrated by the company's compliance to the following international manufacturing standard:

- **EN ISO 13485:2016** - Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

Signed on behalf of the Manufacturer CellPath Limited

Address of Issue CellPath Ltd
Unit 80, Mochdre Enterprise Park
Newtown, Powys
Mid Wales, UK
SY16 4LE

Date of Issue 27/07/2021

Name of Signatory Hannah Moore

Position of Signatory Product Manager

Signature

H Moore
Hannah Moore (Reg No: 2021-09-10-GMT-1)

Synergy Number: 01.564.393

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